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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,588	09/15/2003	Sven Schreder	MERCK-2168D1	8058

23599 7590 03/08/2006

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,588

Applicant(s)

SCHREDER ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/700421.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11-28-05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Applicants' Amendment filed November 28, 2005 is acknowledged. Claims 2, 7 and 8 are canceled. New claim 10 is presented. Applicants state claim 9, although described as "amended" in the Preliminary Amendment, was intended to be a new claim. Accordingly, claims 1, 3-6, 9 and 10 are now under consideration.

The Information Disclosure Statement filed November 28, 2005 (originally, September 15, 2003) fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

The non-patent literature documents cited on that same form PTO-1449 are not scanned and are unavailable to the Examiner.

In the last Office Action the disclosure was objected to because no antecedent basis or support for the amendment to claim 1 is provided in the specification.

The objection is withdrawn because antecedent basis is provided on page 3.

Claims 1-6 were rejected in the last Office Action under 35 U.S.C. 112, second paragraph, because it was asserted the recitation "whereby said preparation possesses improved stability versus one in which a customary binder other than gelatin is used" renders claim 1 vague and indefinite. The metes and bounds of the recitation "improved stability" cannot be precisely determined.

Applicants argue one of ordinary skill in the art would have no problem selecting an appropriate test to measure stability of the presently claimed preparations and would

know when the difference in stability was significant as to qualify as "improved." A reference to page 3 of the specification is made.

Applicants' argument is not persuasive. Page 3 of the specification discloses tablets containing levothyroxine to be stable for at least 2 years at temperatures below 30 degrees C. No comparison to other "customary binders" in this regard is shown. The claims define the invention. While the skilled artisan in the art of formulation chemistry may know the metes and bounds of "customary binder," the specification fails to provide support for the subjective recitation of "improved stability."

The rejection of record under 35 U.S.C. 112, second paragraph, is maintained and presently extended to new claims 9 and 10.

Upon reconsideration the rejection of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent 6,491,946 is withdrawn.

Applicants' arguments with respect to claims 1, 3 and 9 that were rejected in the last Office Action under 35 U.S.C. 102(b) as being anticipated by Israel, M. GB 1, 180,574, and to claims 1-6 that were rejected under 35 U.S.C. 103 as being unpatentable over Israel, M. GB 1, 180,574, in view of Reynolds et al., U.S. Patent 3,808,332, have been considered but are moot in view of the new ground of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds et al., U.S. Patent 3,808,332, in view of Israel, GB 1,180,574.

Reynolds teaches a combination of L-thyroxine and L-triiodothyronine that are physically admixed. Therefore, no organic solvent residues are present. See column 7, lines 65-67. As required by instant claim 3, Reynolds teaches a concentration range of l-thyroxine of 100-300 mcg. Fillers such as lactose, maize starch and microcrystalline cellulose are conventional excipients. Reynolds fails to include gelatin in the combination. However, Israel teaches the inclusion of gelatin in pharmaceutical preparations comprising thyroxine. Therefore, in view of Israel's teaching the utility of gelatin as a customary excipient in preparations comprising thyroid hormones, one skilled in the art of formulation chemistry would have been motivated to prepare a pharmaceutical formulation comprising as actives, levo-thyroxine and liothyronine, with an excipient such as gelatin and fillers that are known in the prior art. Gelatin is known in the prior art as an emulsifying agent or a binder. Nothing unobvious is seen using gelatin as an emulsifying agent or as a binder in such a pharmaceutical preparation, and clear unexpected results are absent.

No claim is allowed.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/661,588

Page 6

Art Unit: 1614

Phyllis Spivack

Phyllis G. Spivack

March 6, 2006

1614

**PHYLLIS SPIVACK
PRIMARY EXAMINER**